

Serial No.: 09/981,337
Docket No.: VAS-5041DIV2
Amendment dated September 8, 2003
Responsive to Office Action of May 7, 2003

REMARKS/ARGUMENTS

Claims 1-80 were pending in the application (with claims 22, 23, 35, 36, and 41-80 withdrawn). Applicants have canceled claims 1-80 and added new claims 81-105. Therefore, claims 81-105 are now pending in the application.

5

Election/Restriction

With regard to the previous election, Applicants have submitted herewith a new set of claims that corresponds to the internally stented PTFE graft of Species II. Applicants believe that none of the new claims falls outside the scope of the subspecies previously elected.

10

Priority

The present claims derive proper support from prior application No. 09/358,350, and thus the present application is not a continuation-in-part of prior application, and the same inventors are involved.

15

Drawings

The objectionable language in the previous claims has been removed by canceling the claims and, therefore, there is no need for the drawing corrections.

20

Specification Objection

The noted features in the previous claims have been removed by canceling the claims and, therefore, the objection to the specification under 37 CFR section 1.75(d)(1) is believed obviated.

25

Claim Rejections Under 35 U.S.C. § 112

Claims 6, 15, and 30 stand rejected under 35 U.S.C. section 112, first paragraph, as containing subject matter allegedly not described in the specification as filed. While not agreeing with the propriety of this rejection, Applicants have removed any problematic language cited by

Serial No.: 09/981,337
Docket No.: VAS-5041DIV2
Amendment dated September 8, 2003
Responsive to Office Action of May 7, 2003

the Examiner from the previous claims by canceling the claims. The present claims derive proper support from the specification as filed.

Claim Rejections Under 35 U.S.C. § 102

5 Anticipation by Myers et al.

Claims 1-4, 6-8, 11-16, 20, 21, 29-32, and 39 stand rejected under 35 U.S.C. §102(b) as being anticipated by Myers et al. (WO 95/05132, equivalent to USPN 5,700,285). Although this rejection has been rendered moot because all of the pending claims have been canceled in favor 10 of the new claims, Applicants will discuss the new claims below and contrast them with Myers, et al. with respect to any features that carry over from the earlier set of claims.

Discussion of New Claim 81

Myers, et al. do not disclose an internally stented graft having a flexible, porous, 15 biocompatible tubular PTFE graft co-axially disposed in contact with and adhered to the outer surface of a stent, the tubular PTFE graft being formed of a plurality of concentric layers of helically-wound PTFE tape. Instead, Myers, et al. disclose a single layer length of PTFE film wrapped around the stent. Indeed, Myers, et al. teach away from providing multiple layers of tape or film around stent because the end result of a single layer of film is a covering which is 20 less than 0.10 mm thick. With reference to the four examples given in Myers, et al. in columns 4-8 (using the col. and line numbers in USPN 5,700,285), none have multiple layers of tape or film around the outside of a stent. Please see Example 1 at col. 5, ll. 54-56, “[E]xcept for the overlapped seemed edges 49, the circumferentially-wrapped covering was only one film layer thick. Also see Example 2 at col. 6, ll. 40-42, “[A]s shown by Fig. 5, the mandrel 43 was then 25 provided with a single layer 51 wrapping of a porous expanded PTFE film 35...” In Example 3 at col. 7, ll. 11-15, the “stent was then provided with a single layer exterior wrapping of the same discontinuously FEP-coated porous expanded PTFE coating used for the exterior wrapping of the stent of Example 1. In example 4, spanning columns 7-8, a PTFE covered wire is braided into a

Serial No.: 09/981,337
Docket No.: VAS-5041DIV2
Amendment dated September 8, 2003
Responsive to Office Action of May 7, 2003

tubular stent and then covered with helically wrapped PTFE film. While being removed from the fabrication mandrel, the stent is everted, placing the PTFE film on the inside of the stent rather than the outside. Please see col. 8, ll. 24-35.

Claim 81 is not obvious in view of Myers, et al., because there is no discussion of
5 providing, on the outer surface of a stent, a tubular PTFE graft formed from a plurality of concentric layers of helically-wound PTFE tape. Example 4 provides a helically wrapped PTFE film of 12 mm width around a braided stent, but the stent is then everted placing the PTFE film on the luminal side thereof. Furthermore, the PTFE film is wrapped so that the edges overlap by only approximately 1 mm so that the resulting tube is essentially one layer, as opposed to “a
10 plurality of concentric layers” as recited in claim 81.

Discussion of new claim 91

Myers, et al. do not disclose an internally stented graft having a flexible, porous, biocompatible tubular PTFE graft co-axially disposed in contact with and adhered to the outer
15 surface of a stent, the tubular PTFE graft having been expanded and completely sintered prior to assembly with the stent. Myers, et al. merely disclose the use of “porous expanded PTFE film” around the stent. There is no mention of completely sintering the PTFE film. The examples explain that the film-wrapped stent (assembled) is placed in an oven set at various temperatures between 360-380 degrees C. for three or four minutes. There is no discussion that this process
20 completely sinters the PTFE material. Furthermore, Applicants respectfully assert that there is a difference in the final product when the PTFE material is completely sintered prior to assembly as opposed to after assembly. For example, it is recognized in the art that completely sintered PTFE will not bond as effectively to other completely sintered PTFE when subsequently heated (see, e.g., Banas, et al., USPNS,749,880). Therefore, Applicants assert that claim 91 is novel
25 over Myers, et al.

Moreover, because of the absence of any mention in Myers, et al. of completely sintering the tubular PTFE graft prior to assembly with the stent, ^{they} would be no motivation to do so and claim 91 is not obvious over Myers, et al.

Serial No.: 09/981,337
Docket No.: VAS-5041DIV2
Amendment dated September 8, 2003
Responsive to Office Action of May 7, 2003

Discussion of new claim 100

Myers, et al. do not disclose a flexible, porous, biocompatible tubular PTFE graft co-axially disposed in contact with and adhered to the outer surface of a stent; with a polymer coating on the stent to facilitate adherence of the stent to the tubular PTFE graft.

5 The Examiner cited the combination of Myers, et al. and Palmaz (USPN 4,776,337) in a 35 U.S.C. section 103(a) obviousness rejection of original claim 33, which provided a polymer coating formed on the stent. Applicants respectfully submit that Myers, et al. in combination with Palmaz does not render the claims pertaining to a polymer coating on the stent obvious to one of ordinary skill in the art. The U.S. Court of Appeals for the Federal Circuit has held that
10 “[t]he PTO has the burden under section 103 to establish a *prima facie* case of obviousness..It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.” In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

15 The Examiner merely states that it would have been “obvious to one of ordinary skill in the art to use in coating on the stent... as taught by Palmaz with the stent-graft of Myers in order to provide a smooth surface thereby reducing the chance of restenosis.” Office Action at page 9. Thus, the Examiner does not point to any discernible suggestion in either Myers, et al. or Palmaz that would lead one of ordinary skill in the art to combine the two references. What the Examiner
20 offers is the unsupported assertion that a skilled artisan would have been motivated to combine the two references.

Such an assertion cannot be used to base a finding of obviousness. Id. The In re Fine Court held that “the Examiner’s bald assertion” that substitution of an element from one reference into another “would have been within the skill of the art” cannot support a finding of
25 obviousness. Id. In the instant case too, the Examiner’s statement about combining Myers, et al. with Palmaz is an assertion that is not adequate to support a 103 rejection of Applicant’s pending claims.

Serial No.: 09/981,337
Docket No.: VAS-5041DIV2
Amendment dated September 8, 2003
Responsive to Office Action of May 7, 2003

Case law unequivocally establishes that the motivation to support a combination of references must withstand scrutiny. The Federal Circuit's discussion of this requirement in In re Rouffet, 149 F.3d 1350 (Fed. Cir. 1998) is instructive. There the Court stated:

5 "[V]irtually all [inventions] are combinations of old elements." Environmental Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 698, 218 U.S.P.Q. 865, 870 (Fed. Cir. 1983); see also Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1579-80, 219 U.S.P.Q. 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore an Examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." Sensonics, Inc. v. Aerosonic Corp., 81 F.3d 1566, 1570, 38 U.S.P.Q. 2d 1551, 1554 (Fed. Cir. 1996). To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the Examiner to show a motivation to combine the references that create the case of obviousness. Id. at 1357.

10 The court then noted that the Board had failed to "explain what specific understanding or technological principle within the knowledge of one of ordinary skills in the art would have suggested the combination." Id. (emphasis added). Finding that the Board had "merely invoked the high level of skill in the . . . art," the court stated:

15 If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirements stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness. Id. at 1357-1358 (emphasis added).

20 Applicants submit that, in the present case, the purported motivation for the cited combination fails to identify the "specific understanding or technological principle within the knowledge of one of ordinary skill in the art" that would lead to the specific combination on which the rejection is based. See also Ex Parte Clapp, 227 U.S.P.Q. 2.d 1300 (Bd. Pat. App. & Inter. 1985) (When the references do not explicitly suggest combining their teachings, the

Serial No.: 09/981,337

Docket No.: VAS-5041DIV2

Amendment dated September 8, 2003

Responsive to Office Action of May 7, 2003

Examiner must present a convincing line of reasoning to support the rejection.) Thus, a conclusory statement that a reference can be used to improve a certain technique hardly amounts to a reasoned explanation of why it would have been proper to combine that reference with another reference. While the Federal Circuit has held that the recognition of some advantage or

5 expected beneficial result may be a rationale for combining references, that recognition must exist impliedly or explicitly in the references or be drawn from a convincing line of reasoning based on established scientific principles or legal precedent. In re Sernaker, 702 F. 2d 989, 994 (Fed. Cir. 1983).

Accordingly, the motivation cited by the Examiner is insufficient to support the
10 combination and thus insufficient to support a case of *prima facie* obviousness.

Thus, an attempt to combine Myers, et al. with Palmaz by simply assuming that these two references can be combined does not comport with the Federal Circuit's well established rule that the mere fact that the references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re
15 Mills, 916 F. 2d 680 (Fed. Cir. 1990). See also In re Laskowski, 871 F.2d 115, 117 (Fed. Cir. 1989).

The Federal Circuit has stated that it is impermissible simply to engage in hindsight reconstruction of the claimed invention, using the Applicant's structure as a template and selecting elements from references to fill the gaps. Interconnect Planning Corporation v. Feil, 774
20 F.2d 1132, 1143 (Fed. Cir. 1985). The references themselves must provide some teaching whereby the Applicant's combination would have been obvious. In re Gorman, 933 F.2d 982 (Fed. Cir. 1991). For all of the foregoing reasons, Applicant submits that the attempted combination of references is based on impermissible hindsight reconstruction and the references do not provide any teaching that would have rendered Applicant's invention obvious. Therefore,
25 claim 100 is believed allowable over Myers, et al. alone, or in combination with Palmaz.

Serial No.: 09/981,337
Docket No.: VAS-5041DIV2
Amendment dated September 8, 2003
Responsive to Office Action of May 7, 2003

Discussion of Double patenting rejection

With regard to the obviousness-type double patenting rejection of original claims 1, 2, 7 14-21, 26-34, 37, and 38, Applicants presume that the same rejection will apply to the new claims, and therefore a Terminal Disclaimer is submitted currently herewith.

5

Petition For Extension of Time

Applicants believe that a One-Month extension of time to reply is in order under the provisions of 37 CFR §§1.136 and 1.191 and, therefore, Applicants request such an extension. Applicants also request for such further extension of time as the Commissioner deems necessary.

10

Fees Due to File This Amendment

The amendment has resulted in no additional net claims, and thus no claim fees are believed necessary. However, the Commissioner is hereby authorized to charge deposit Account No. 50-1225 as fees for any new claims if deemed appropriate.

15

Conclusion

Accordingly, in view of the above amendments and remarks, it is submitted that the new claims 81-105 are in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution 20 of the subject application, the Examiner is invited to call the undersigned at (949) 250-6801.

Serial No.: 09/981,337
Docket No.: VAS-5041DIV2
Amendment dated September 8, 2003
Responsive to Office Action of May 7, 2003

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any request for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225.

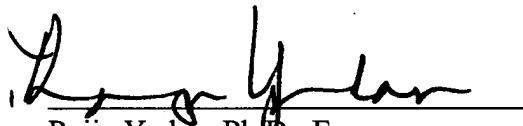
5

Date: September 8, 2003

10

15

Respectfully submitted,



Rajiv Yadav, Ph.D., Esq.
Registration No. 43,999
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6801
Facsimile: (949) 250-6850
Customer No. 30452